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**REMARKS**

Upon entry of the above amendments, only claims 1-4, 7-9, 17-20, 23, 24, 29, 30, and 34 will be pending. Applicants reserve the right to pursue subject matter that will no longer be pending, after the amendment above or which has not yet been pursued, in a related application. These amendments are introduced for the purpose of facilitating prosecution, to reduce the number of open issues, or to place the claims in better form for appeal, and are not narrowing. The claim amendments add no new matter as there is basis in the specification on page 13, paragraphs 0038 and 0039, and in Figure 1, for example. Thus, entry of the above amendments is proper.

Applicants extend their appreciation to the Examiner for discussing the claim amendments presented above with the undersigned representative. In addition to these claim amendments, the Examiner and undersigned representative discussed U.S. Patent No. 5,505,700 and the meaning it affords the term "internal electrode," which is addressed in greater detail hereafter.

**Restriction Requirement**

The final Office action confirmed a four-way restriction requirement advanced telephonically on February 20, 2004 to Applicants' representative, at which time Applicants' representative provisionally elected the claims of Group I, namely independent claims 1 and 17 and the claims depending there from. Applicants hereby affirm that election, with claims 1-4, 7-9, 17-20, 23, 24, 29, 30, and 34 being readable on the elected species. Applicants respectfully request reconsideration of the elected subject matter.

**Art Rejections**

Applicants respectfully traverse the rejection of claims 1-4, 7-9, 17-20, 23-26, and 29-34 under 35 U.S.C. § 102(b) as allegedly anticipated by, or, in the alternative, as supposedly obvious under 35 U.S.C. § 103(a) over Leone, et al. (U.S. Pat. No. 5,505,700), for the reasons described hereafter.

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Rejection Under 35 U.S.C. § 102(b)

*Prima facie* anticipation is established only when the cited document provides an enabling disclosure and describes, either explicitly or inherently, all of the elements of the rejected claim(s). Independent claims 1 and 17 are amended herein to more clearly specify that the first and second electrodes are on the exterior surface of the catheter (e.g., specification on page 13, paragraphs 0038 and 0039 and Figure 1). The '700 patent fails to anticipate any of the pending claims because it requires that one of the catheter electrodes is an internal electrode.

While not specifically defined, the '700 patent repeatedly refers to one of the electrodes in the disclosed catheters as an "internal electrode." For example, the specification at column 2, lines 47-53, broadly refers to the invention as a catheter comprising one or more balloons, an internal electrode, and an integral electrode, and the claims are consistent with this characterization. This characterization of the subject matter of the '700 patent precludes an interpretation that the term "internal" refers to the position of the electrode with respect to two balloons because some embodiments include only one balloon. The term "internal" also does not pertain to an arrangement in which a catheter electrode is configured with an electrode external to a subject's body, as the background section makes it clear that the disclosed catheters are distinct from prior art catheters of this type (e.g., column 2, lines 5-23).

Rather, the consistent use of the term "internal electrode" throughout the '700 patent indicates that the term precludes placement on the exterior surface of the catheter. For example, Figure 3 and the specification at column 5, lines 41-42, of the cited patent discuss a catheter embodiment in which a porous membrane covers the internal electrode. In this embodiment, the electrode clearly is not on the exterior surface of the catheter assembly because it is located beneath the membrane layer. Also, the cited patent at column 6, lines 27-28, refers to the integral electrode 66 in Figure 4 as "external," which by inference precludes the internal electrode from being on the catheter exterior.

This use of the term "internal" also precludes an interpretation that the electrode 35 in Figure 2 is on the exterior surface of the catheter assembly. The shaded rendition of catheter

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treatment length 34 does not represent porous or osmotic passageways because the description at column 4, lines 51-57, makes it clear that the catheter contains either ports 19 or pores or osmotic passageways. Figure 2 therefore depicts the catheter configuration with ports 19 only, with the shaded rendition of treatment length 34 thus representing a structural feature other than pores or osmotic passageways. Indeed, the shaded rendition of catheter treatment length 34 is consistent with drawing conventions in which elevations within a structure are distinguished by shading. For example, elevations of distinct layers within electrical insulation are represented by shading in the tubular, cross-sectional drawings that depict such structures. MPEP 608.02 IX. Consistent with depicting various elevation layers of electrical insulation by shading, the shaded tubular structure in Figure 2 appears to represent the catheter interior and not the catheter exterior, which is not shown. Therefore, the internal electrode 35 in Figure 2 must not be located on the exterior surface of the catheter assembly.

As further evidence that the internal electrode in Figure 2 is not on the exterior catheter surface, the Office characterized the catheters disclosed in the '700 patent as being useful for iontophoresis (e.g., paper 19, page 6), and the patent states that the main use of the disclosed catheters is for electroosmotic infusion (e.g., column 2, lines 40-42 and column 5, lines 23-27). The cited patent and accepted meanings of the terms "iontophoresis" and "electroosmotic infusion" involve the passage of molecules through a semi-permeable barrier. For example, the '700 patent specifies at column 1, lines 64-66, that iontophoresis technology "uses an electrical potential or current across a semi-permeable barrier to drive ionic medicaments toward the target treatment site (emphasis added)." Also, "electroosmosis" is defined as "the diffusion of a substance through a membrane in an electric field (emphasis added)" by a scientific dictionary (e.g., [http address cancerweb.ncl.ac.uk](http://address.cancerweb.ncl.ac.uk)). Because the cited patent and accepted meanings in the art make it clear that iontophoresis and electroosmosis involve movement of molecules across a semi-permeable barrier, Figure 2 of the '700 patent should be interpreted as disclosing the interior surface of the catheter treatment length 34 without the requisite semi-permeable barrier. Further supporting this interpretation is that if the electrode depicted in Figure 2 of the '700 patent was on an exterior surface of the catheter, the electric field generated between electrodes 35 and 36 would not be across a semi-permeable barrier, but to one side of it.

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Thus, the drawings and the specification of the '700 patent consistently refer to an "internal electrode" as an electrode not located on the exterior surface of the catheter. For these reasons, Applicants respectfully request that the Office withdraw the rejection under 35 U.S.C. § 102(b).

Rejection Under 35 U.S.C. § 103(a)

Applicants also traverse the alleged obviousness of claims 29-34 in view of the '700 patent. As an initial matter, they note that entry of the amendment above will obviate this rejection as to claims 31-33, in which subject matter Applicants 'expressly reserve their rights. Claimed matter is *prima facie* obvious only when the cited document or combination of documents teaches or suggests all of the claimed elements, the person of ordinary skill in the art was motivated to modify the document(s) as suggested in the Office action, and there was a reasonable expectation of success. *See* MPEP 2142, *et seq.*

As described above, the claimed catheters, which include electrodes located on the exterior surface of a portion of the catheter body, differ from the catheters disclosed in the '700 patent because the latter require an internal electrode. Modifying an internal electrode in catheters of the '700 patent to an external electrode is not an obvious selection, and therefore the '700 patent does not teach or suggest such a modification. The '700 patent states the internal electrode is useful for driving medicament away from the catheter towards the vessel wall by electroosmotic infusion (e.g., column 5, lines 22-27). Because the cited patent discloses placement of one electrode internally within the catheter to push the medicament away from the catheter, the ordinarily skilled artisan would find no reason to shift the placement of the electrode to the exterior surface of the catheter. Such a shift might result in a catheter that does not effectively work for its intended purpose of repelling medicament from the catheter.

The '700 patent also suggests that the disclosed catheters are useful for "electroporation" (column 7, lines 39-43), as that term is unconventionally defined, i.e., as "the electrical breakdown of cells which contain substances such as hemolytic compounds, genes, and the like." *Id.* Accordingly, there was no motivation for a person of ordinary skill in the art to modify the

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internal electrode configuration for the purpose of conducting electroporation procedures as taught by Applicants since the cited patent reported that goal already was accomplished.

Because the '700 patent does not teach or suggest modifying the internal electrode configuration to provide an exterior electrode configuration, and because there was no motivation for the person of ordinary skill in the art to make such a modification, the claimed subject matter is not obvious. Accordingly, Applicants respectfully request that the Office withdraw the rejection of the pending claims under 35 U.S.C. § 103(a).

### CONCLUSIONS

Applicants respectfully submit that, after entry of the amendment above, all pending claims will be in condition for allowance, and they earnestly solicit an early notice to such effect. That said, should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at (858) 623-9470 so that they may be promptly resolved.

In the unlikely event the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to the credit card disclosed in form PTO-2038 filed with this document.

Respectfully submitted,

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